EXHIBIT C

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1
           IN THE UNITED STATES BANKRUPTCY COURT
           SOUTHERN DISTRICT OF WEST VIRGINIA
2
                  (CHARLESTON DIVISION)
3
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4
    IN RE: ETHICON, INC. PELVIC : MASTER FILE NO.
5
    REPAIR SYSTEM PRODUCTS : 2:12-MD-02327
    LIABILITY LITIGATION :
6
                               : MDL NO. 2327
    THIS DOCUMENT RELATES TO
7
                               : JOSEPH R. GOODWIN
    ALL WAVE 8 AND SUBSEQUENT : U.S. DISTRICT JUDGE
    WAVE CASES AND PLAINTIFFS :
9
10
11
              Deposition of MARK ELLERKMANN, M.D.
                    Towson, Maryland
12
13
                Friday, October 12, 2018
14
                         1:05 p.m.
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23
    Reported by: Linda M. Bahur, RPR
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	PACE DITCH	· · · · · · · · · · · · · · · · · · ·
	Page 2	Page 4
	Deposition of MARK ELLERKMANN, M.D., held at:	$ \begin{array}{ccc} 1 \\ 2 \end{array} $ INDEX
2	SHERATON BALTIMORE NORTH HOTEL	3 EXAMINATION
3	903 Dulaney Valley Road	⁴ Witness Name Page
4	Towson, MD 21204	5 Mark Ellerkmann, M.D. 6 Direct By Mr. Faes
5	Pursuant to agreement, before Linda M. Bahur,	⁷ Cross By Mr. Snell 138
6	a Notary in and for the State of Maryland.	PLAINTIFF EXHIBITS
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16 17		DEFENSE EXHIBITS
18		(Exhibit No. 1 retained by Mr. Snell)
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1	APPEARANCES	1
2	ON BEHALF OF THE PLAINTIFF:	² PROCEEDINGS
3	Andrew N. Faes, Esquire	³ (Plaintiff Exhibit Nos. 1-4 were marked
4	Wagstaff & Cartmell, LLP 4740 Grand Avenue	⁴ for identification.)
	Suite 300	⁵ Whereupon
5	Kansas City, MO 64112	6 MARK ELLERKMANN, M.D.
	(816) 701-1100	⁷ being first duly sworn, as hereinafter certified,
6	afaes@wcllp.com	8 testifies as follows:
,	ON BEHALF OF DEFENDANT:	9 EXAMINATION BY MR. FAES:
8	or berning of bereithing.	Q Good afternoon, Dr. Ellerkmann. My
9	Nils B. (Burt) Snell, Esquire	¹¹ name is Andrew Faes and I represent various
10	Butler Snow, LLP	plaintiffs in this litigation, and I'm here today
	500 Office Center Drive Suite 400	13 to take your deposition regarding the Prolift
	Duill 700	
12	Fort Washington, PA 19034	14 case Do you understand that?
	Fort Washington, PA 19034 (267) 705-4910	14 case. Do you understand that?
13		15 A Yes, I do.
13 14	(267) 705-4910	A Yes, I do. And you understand that you're under
13	(267) 705-4910	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right?
13 14 15	(267) 705-4910	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right? A Yes.
13 14 15 16	(267) 705-4910	15 A Yes, I do. 16 Q And you understand that you're under 17 oath and you're sworn to tell the truth; right? 18 A Yes. 19 Q And if for any reason during the course
13 14 15 16 17 18 19	(267) 705-4910	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right? A Yes. Q And if for any reason during the course of the day I ask you a question that doesn't make
13 14 15 16 17 18 19 20	(267) 705-4910	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right? A Yes. Q And if for any reason during the course of the day I ask you a question that doesn't make sense to you, just let me know and I'll try to
13 14 15 16 17 18 19 20 21	(267) 705-4910	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right? A Yes. Q And if for any reason during the course of the day I ask you a question that doesn't make
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13 14 15 16 17 18 19 20 21	(267) 705-4910 burt.snell@butlersnow.com	A Yes, I do. Q And you understand that you're under oath and you're sworn to tell the truth; right? A Yes. Q And if for any reason during the course of the day I ask you a question that doesn't make sense to you, just let me know and I'll try to rephrase the question. All right?

Case 2:12-md-02327 Document 7023-3 Filed 10/25/18 Page 4 of 17 PageID #: 184111 Mark Ellerkmann, M.D. Page 14 Page 16 ¹ probably around 2010. Somewhere in that range. 1 percentage? 2 Q And when was the last time that you A I can put a general percentage on that. ³ implanted a Prolift device? It was probably less than 5 percent. Q And that's all complications, not just Sometime around the same period of 5 time. ⁵ erosion? A It depends on what complication if we 6 Q And the Prolift+M? ⁷ look at the no classification. You know, if we're A I can't give you an exact date. 8 O You kind of lumped the Gynemesh PS talking about Class 1 complications, maybe higher. Prolift and Prolift+M all together and state that Urinary tract infections, something like that. 10 you've utilized them in hundreds of patients. Do But if we're talking about specifically mesh 11 you have any kind of breakdown of how many exposure, mesh erosion, less than 5 percent. 12 Gynemesh PS devices you've implanted in a patient Q But as you sit here today, you can't 13 or patients? give me, say, a denominator of the total number of 14 A I would say Gynecare -- that Gynemesh cases of Prolift or the numerator of the total ¹⁵ PS, I would say I was using that prior, obviously, number of cases of Prolift? 16 to launch a Prolift for prolapse repair. I would 16 MR. SNELL: Object to form. Go ahead. say the breakdown would be probably around 30 17 Q Complications? MR. SNELL: Object. Form. 18 percent Gynecare Gynemesh PS and 70 percent --18 19 just under 70 percent for Prolift. 19 A No. My overall complication rate with 20 Q And for Prolift+M, it's less than 5 respect to Prolift, less than 5 percent. 21 percent or less than 2 percent? Q And would you agree with me that that, 22 22 since you can't give me the numerator or the A That is correct. Right. 23 Q Is it accurate to say that you probably denominator as you sit here today, that that 5 ²⁴ implanted the ProliftM on less than five percent isn't based on any formal analysis that Page 15 Page 17 1 you've done of your complication rate? ¹ occasions? MR. SNELL: Object. You're misstating. A No, I wouldn't say that's accurate. ³ Not less than five occasions, but less than 5 A No, I would not agree with that,

4 actually, because I did look at my complication

rate and it is generally less than 5 percent.

MR. FAES: Okay. Well, Counsel, if

⁷ that's an opinion he's going to express at trial,

8 we're going to request production of the data from this database that substantiates his opinion that

his complication rate is 5 percent.

MR. SNELL: We'll take that up. That's 12 for me. We'll take that up.

Q Same question with regard to the 14 Gynemesh PS. Have you done any kind of tracking of a complication rate of your use of Gynemesh PS?

MR. SNELL: Hold on. Hold on. I'm 16 going to object to the form and foundation of the question to the extent it assumes Gynemesh PS to be different than Prolift. You can go ahead and 20 answer.

21 A So Counsel, I've told you that I kept a ²² record of every surgery that I've done since I was ²³ a fellow. That included the use of Gynemesh PS 24 Prolift.

⁴ percent of the time.

O Okay. Have you ever tracked a 6 complication rate for the Prolift based on your personal use in your office?

A So I keep a database of my surgery, ⁹ every surgery I've done even as a fellow. Not as ¹⁰ a resident but as a fellow. I did my training 11 here. And of that database, I kept a complication ¹² rate and still do.

13 Q And I don't see anywhere in your expert 14 report where you say that you intend to state an opinion as to what your complication rate is with 16 the Prolift®. Is that an opinion that you intend to offer in this case?

18 MR. SNELL: I'm going to object to the ¹⁹ characterization. Go ahead.

20 A I can offer an opinion regarding my complication rate with respect to Prolift and that was that it was extremely low.

23 O So extremely low. Can you put a numerator on that or a denominator or a

Page 38

1 the materials listed in Exhibit 3?

1 supplemented it with sor

- ² A Better part of four weeks.
- Q So how many hours would you say you spent on that?
- A Close to 120 hours. That includes
- 6 looking at these articles, refreshing my memory,
- ⁷ and composing the manuscript, the expert report.
- Q So the 120 hours includes both the
- 9 review of the materials and the writing of the 10 report; right?
- 11 A That's correct. Yes.
- Q How many hours would you say you spent
- ¹³ actually drafting your report as opposed to
- 14 reviewing materials?
- A Well, I took notes as I reviewed the
- ¹⁶ materials and I composed my report. I had two
- ¹⁷ computers going at the time, two screens. So a
- 18 lot was done simultaneously, so it's hard to break
- ¹⁹ it down.
- Q Okay. In your reliance list, you've
- 21 got --
- MR. FAES: Counsel, is this his current
- ²³ reliance list or is there a supplemental one that
- ²⁴ I might be missing out on?

1 supplemented it with some materials that you had

Page 40

Page 41

- ² reviewed and relied on on your own; is that
- 3 correct?
- A That is correct.
- Q Did you feel like that you had
- 6 everything you needed in order to form your
- ⁷ opinions in this case?
- A Well, my opinions are formulated in
- ⁹ part due to literature and also my own clinical
- 10 experience. So in terms of written literature
- 11 that I reviewed, this served as the bulk of that.
- 12 Yes.
- Q Did you do any of your own independent
- 14 literature searching for peer-reviewed literature
- 15 on Prolift®?
- A I did, and that's what I'm saying.
- 17 It's the articles that weren't included in this
- 18 are referenced and submitted ultimately in what we
- ¹⁹ have before us here.
- Q And I see that on your reliance list
- 21 that you did review the testimony of a couple
- 22 Ethicon employees? A Piet Hinoul and a Marty
- 23 Wiseberg?
- A I'm not sure I reviewed those in

Page 39

- MR. SNELL: No, I think this is his
- ² list. I don't think that he has a pending
- ³ supplemental one.
- 4 MR. FAES: Everybody else supplemented
- ⁵ theirs, so I wasn't sure. I got brought in late
- 6 on this so I just wanted to make sure that there
- ⁷ wasn't a supplemental one that I wasn't aware
- 8 of.
- 9 MR. SNELL: Not that I know of.
- THE WITNESS: This looks current to me.
- MR. SNELL: Okay.
- 12 BY MR. FAES:
- O Who created Exhibit No. 3?
- ¹⁴ A Mr. Snell's firm.
- Q Okay. So did Mr. Snell's firm provide
- ¹⁶ you with all of the documents and materials listed
- ¹⁷ in Exhibit No. 3?
- A Did they provide me with them all?
- 19 Q Yes
- A They comprised this report. Yes. And
- there's other things are included in this that I
- ²² shared with them that I was using in my report.
 - Q Okay. So it's accurate to say that
- 24 they provided a large majority and then you

- ¹ particular. No.
 - ² Q Okay.
 - ³ A I may have glanced at them. Some of
 - ⁴ these articles that are listed here are articles I
 - 5 am familiar with because either my fellows wrote
 - 6 them or co-workers or colleagues. So that doesn't
 - ⁷ mean I read them back to back. I'm familiar. I
 - 8 spent my last 20, 25 years reading the literature,
 - ⁹ so that's how I spend a lot of my evenings.
 - Q So if I understood you correctly,
 - So it i anderstood you confeetly
- $^{11}\,$ you're not sure if you reviewed Piet Hinoul or
- ¹² Marty Wiseberg's deposition testimony?
- A Yes. I'm not sure I've reviewed those in particular now.
 - in particular now.
 - Q Are there other materials that are
- ¹⁶ listed in your reliance list that you haven't
 - ⁷ reviewed?
- A I would say that most of these I have
- ¹⁹ reviewed. Either read in their entirety or
- ²⁰ reviewed.

21

24

- Q Most but not all?
- A Right. So some of the depositions you
- 23 said O'Toole. What page is that on?
 - Q It's the second-to-last.

	Mark Ellerkmann, M.D.						
	Page 42		Page 44				
1	Unfortunately, you guys never put page numbers on	1	settled for a nominal amount of money to cover				
2	this, which I think they do on purpose.	2	court costs or something like that it was.				
3	A Yes. So Counsel, some of the	3	Q Were you deposed in either of those				
4	depositions and some of the email communications I	4	cases?				
5	would have probably not reviewed. I was looking	5	A I was deposed, I know, in the first				
6	more at Level 1, Level 2 literature as I did my	6	one. Probably both of them, actually.				
7	report.	7	Q And where were you employed at the time				
8	Q So as we sit here today, is there any	8	that those occurred?				
9	kind of list out there that reflects what you	9	A Greater Baltimore Medical Center.				
10	actually did review and rely on in coming to your	10	Q And do you recall the name of any of				
11		11	the law firms involved in those cases?				
12	A I would say the list before us is	12	A No.				
13		13	Q Do you recall the name of any of the				
14	-	14	plaintiffs in those cases?				
15		15	A One plaintiff was Loftus.				
16	reviewed?	16	Q And can you spell that for the				
17	MR. SNELL: Objection as to scope of	17	reporter, to the best of your memory.				
18		18	A Yes, L-O-F-T-U-S. And the other				
19	A I would say yes to that.	19	plaintiff I can't remember offhand.				
20		20	Q And you're currently licensed in the				
21		21	state of Maryland; right?				
22	haven't reviewed the deposition testimony of any	22	A Yes.				
23	-	23	Q And is that the only state where you're				
24		24	currently licensed?				
	·						
	Page 43		Page 45				
1	Q This Edition withouses that worked for	1	A Yes.				
2	r	2	Q And in the past, you've been licensed				
3	11 Well, at least those two that you've	3	in the state of Meine'l				
1 4			in the state of Maine?				
	listed here. No, I have not reviewed those. I	4	A Correct.				
5	think that's fair to say.	5	A Correct.Q But that license is no longer active?				
5	think that's fair to say. Q Okay. Doctor, have you ever been a	5 6	A Correct.Q But that license is no longer active?A That's correct.				
5 6 7	think that's fair to say. Q Okay. Doctor, have you ever been a party to a lawsuit?	5 6 7	A Correct.Q But that license is no longer active?A That's correct.Q When did you let that license lapse?				
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	think that's fair to say. Q Okay. Doctor, have you ever been a party to a lawsuit? A Yes. Q How many times? A Twice I'm aware of. Q And what was your role in those cases? A I was a defendant. Q In both cases? A Both cases, yes. Q And were they both medical malpractice cases? A Yes. Q And when did those two cases occur? A Yeah. One case was sometime in the first case, I was a fellow, and that would have been 2000, 2001. And then again about five years later I don't know when they were finally	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A Correct. Q But that license is no longer active? A That's correct. Q When did you let that license lapse? A When I moved to Maryland in 1998. Q Okay. Have you ever had any are those the only two states where you've ever been licensed? A Yes. Q Have you ever had any action whatsoever taken against your medical license? A No. Q Never had any disciplinary action taken? A No. Q Never had any orders of compliance issued? MR. SNELL: Objection. Asked and answered already.				
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Case 2:12-md-02327 Document 7023-3 Filed 10/25/18 Page 7 of 17 PageID #: 184114 Page 66 Page 68 ¹ think I've stated that a few times now. ¹ ask you what warnings they thought should be in ² the IFU for one of their polypropylene medical Q Sorry. Are you done? I didn't mean to ³ devices, whether orally or written? ³ interrupt you. MR. SNELL: Objection. Can you read A No. Q Have you ever drafted the IFU for a that question back? 6 medical device? (The last question was read into the ⁷ record.) A No, I have not. 8 Q Have you ever worked on warnings for a MR. SNELL: Are you asking did someone at Ethicon ask him what warnings that Ethicon, medical device? 10 they thought? A No, I have not. 11 Q Have you ever worked on warnings for a 11 MR. FAES: So let me see -prescription drug? 12 MR. SNELL: I don't know if you meant 12 13 A No, I haven't, but may I go back to 13 that. 14 14 your answer just previously? Because something MR. FAES: Let me see I can reask it. 15 came to my mind. 15 MR. SNELL: I think I know what you're 16 Q Sure. 16 trying to ask but the question was really --17 A I am actually on a board of advisors BY MR. FAES: ¹⁸ for a development that's currently R&D. We've Q During your time consulting for Ethicon 19 just actually received an N.I.H. grant for a new and Johnson & Johnson, did anyone at Ethicon ever 20 type of pessary -- pessary, P-A-S-S-A-R-Y [sic] -ask you your opinion regarding what warnings you 21 working with colleagues at Dartmouth-Hitchcock in thought should be in a polypropylene mesh device? ²² Hanover, New Hampshire. A Not that I'm aware of specifically. 23 23 Q Would you agree with me that you never So to that end, I have counseled and ²⁴ provided Counsel regarding warnings for pessary ²⁴ worked on warnings for a Class 3 medical device? Page 67 Page 69 ¹ use. A I would agree. I mean, I think we all ² know that these devices were elevated to a Class 3 Would you agree with me that you've ³ never worked on the warnings for a polypropylene ³ device at one point. But at that point in time, 4 mesh device? 4 no, I never worked directly with that. 5 MR. SNELL: Object to form. Q Would you agree with me that physicians A Other than providing feedback at should be made aware of all the significant safety ⁷ various summits and advisory meetings during my risks associated with the Prolift in the IFU? 8 time as a preceptor with Gynecare or AMS for that MR. SNELL: Objection. Asked and 9 matter. answered. 10 10 Q So you actually provided feedback at A Yes. I've answered that. I would 11 seminars for Ethicon and Johnson & Johnson 11 disagree with that, Counsel. I think that the IFU regarding warnings that were in the IFU for their 12 is intended as a general guideline. Pelvic ¹³ polypropylene mesh devices? 13 surgeons are made aware of risks of pelvic surgery 14 14 when they're resident doctors when they do their A I would state it more different. I

- ¹⁵ would state is differently, Counsel. I would say ¹⁶ at various workshops and industry-sponsored ¹⁷ summits, be they in Minnesota or in New Jersey, 18 round table discussions that we had, we shared 19 information with one another about our clinical ²⁰ experience, and I suspect that that information ²¹ was tabulated and looked at and ultimately played ²² a role in formulation of IFUs.
- O So during your time consulting for
- 24 Ethicon specifically, did anyone at Ethicon ever
- first episiotomy. They know that can result in 16 dyspareunia. 17 I mean, we all have a fund of knowledge of knowing complications of surgery whether we're using mesh or native tissue. 20 Q So if a corporate witness for Ethicon and Johnson & Johnson testified that that was the 22 standard that Ethicon and Johnson & Johnson should ²³ follow, you would disagree with that? 24 A Yes, I would.

Page 74 Page 76 1 A Yeah. I don't know what you mean by 1 you to break --² that. Physician's experience and clinical MR. FAES: I don't think I am. ³ experience and knowledge base varies. So is mine 3 BY MR. FAES: ⁴ different than my mentor's, Dr. Bent or my Q Let me ask the question and ask you to ⁵ colleague, Dr. Harry Johnson? It may very well ⁵ focus on the question if you can. ⁶ be. It most certainly is. My clinical experience Would you agree with me that you might ⁷ is my clinical experience. It's unique to me. 7 know about a complication from your own experience O Would you agree with me that you might that another doctor might not know about? MR. SNELL: Objection. I think that ⁹ know about a potential complication from your own ¹⁰ experience that another doctor might not know was asked and answered. 11 about? 11 A Okay. So I might have a complication 12 MR. SNELL: Objection. 12 that another doctor might not know about. I mean, 13 A I would agree that there are 13 that's obvious. To me, I might have a 14 complications I've had that other doctors may not 14 complication with a surgical procedure that I'm 15 have had and vice-versa. That's certainly true in doing that another doctor would not have ¹⁶ clinical practice. We all have unique experienced and would not know about. ¹⁷ complications, and I think if you practice long 17 Q Have you ever studied the question of 18 enough, you'll probably have every complication in what information needs to be in an IFU, 19 the book at some point in your career. instructions for use? 20 Q So you'd agree with me, then, that 20 A Have I ever studied that? I think I've another doctor has an experience that he might not answered this before. I'll answer it again. know about; correct? My understanding of an IFU is that it 23 provides a general background and guidance noting MR. SNELL: Objection. Misstates. 24 potential risks and complications of a medical A I'm not quite sure where you're going Page 75 Page 77 ¹ with this except to say that we've all experienced ¹ device, if that's what we're talking about, ² unique complications that another doctor may not ² without needing or being required to list every ³ have experienced, and that's why we have M&M potential complication or risk related to it. ⁴ conferences and that's why we call colleagues when Q Are you relying on any objective ⁵ we have a unique complication and pick each ⁵ standard from any source for that opinion? 6 other's brains. I mean, that's what a collegial A Any objective standard? Have I read ⁷ that as a specific guideline? No. That is my own ⁷ relationship is about. Q Right. I think you're maybe during my career.

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⁹ misunderstanding my question. I'm not asking you ¹⁰ about whether another doctor might have 11 experienced a different complication than you 12 haven't experienced. I'm asking about 13 complications that another doctor might not know ¹⁴ about. So I'm going to reask the question again

¹⁵ and ask you to focus on that. 16 MR. SNELL: Hold on. I'm going to ¹⁷ object because your questions were about experiencing complications. It wasn't about ¹⁹ knowledge. 20 MR. FAES: No. It's about 21 complication.

22 MR. SNELL: Complications experience. 23 You asked him two or three times and he testified ²⁴ to that. Now you're changing. I just don't want

general understanding of IFUs that I've understood Q Would you agree with me that you're not a biomedical engineer? MR. SNELL: Objection. A I would disagree with that, Counsel. I think I don't have a degree as a bioengineer, I don't have a Ph.D or a doctorate, but I have a lot ¹⁶ of experience in reference to the use of polypropylene mesh and pelvic reconstructive surgery, and, as such, I have been privy to how polypropylene mesh reacts in the human body. I've ²⁰ been a participant at various summits and industry 21 meetings where we've looked at and evaluated properties of polypropylene mesh. Q So you hold yourself out to the public

²⁴ as a biomedical engineer; is that accurate?

Case 2:12-md-02327 Document 7023-3 Filed 10/25/18 Page 9 of 17 PageID #: 184116 Page 90 Page 92 1 Q Would you agree with me that Ethicon 1 you would disagree with that? ² did not design the mesh arms of the Prolift to MR. SNELL: Objection. Foundation. ³ deform? ³ Misstates the evidence. A Deform in what way? Mesh arms are able A I think that any surgery can lead to ⁵ to conform and to be pliable. So can they deform ⁵ contraction; okay? So that's a known risk of any 6 as pliability and deformable? I'm not sure. When ⁶ surgery we do, is contraction. ⁷ you place the Prolift and you place the arms Q Would you agree with me that excessive 8 through the cannula, once the cannulas are contraction or shrinkage of the tissue surrounding removed, the mesh arms remain in place. the mesh is a potential adverse event of the 10 So do they deform once they're in Prolift procedure? place? Are they incorporated into the tissue? 11 MR. SNELL: Objection. Form. 12 Q My question is do you agree that 12 A I don't think it's specific to the 13 Ethicon didn't design the mesh to deform? 13 Prolift procedure. I don't think it's specific to 14 MR. SNELL: Objection. Asked and the polypropylene mesh. I think it's specific to surgery in general that one can have contraction 15 answered. and shrinkage of tissue. I have seen this with 16 A I think the mesh was designed to be very pliable, and in being pliable, pliability native tissue repair. Seen that with posterior, allows the mesh to deform but in a positive way. anterior colporrhaphy without the use of mesh or Q So you believe that Ethicon did design 19 permanent suture. the mesh to deform but only in a positive way? 20 Q Right. But I'm asking specifically 21 MR. SNELL: Object. Misstates. about mesh and excessive shrinkage --22 A I believe that Ethicon designed a A Right. polypropylene microporous mesh to be compatible, 23 Q -- and contraction. Strike that. ²⁴ biocompatible and to provide for native tissue ²⁴ Excessive contraction or shrinkage of tissue Page 91 Page 93 ¹ in-growth to provide for anatomical repair of the ¹ surrounding the mesh. Is that a potential adverse ² prolapse. And I would need to see what the ² reaction of the Prolift mesh? ³ definition of deformity is before I answer that MR. SNELL: Objection. Asked and ⁴ question definitively. answered. Q So as you sit here today, do you know A And I've answered that question. My ⁶ whether or not one of the intentions of the answer to that is no, I do not believe it's ⁷ Ethicon designers, when designing the Prolift related specifically to the mesh. Q And so you believe that that's arms, was that the mesh would deform? A I don't know specifically if that was incorrect information? 10 the word they used in designing the mesh not 10 A I'm saying that that information is 11 relevant to the surgery in general and not ¹¹ deforming. 12 Q Would you agree with me that Ethicon specific to the implant. 13 did not design the Prolift mesh to shrink? Q Do you think that that is an A They did not design the mesh to shrink. 14 appropriate warning for Ethicon to put in their -in the adverse reaction section of the IFU for 15 That's correct. 16 Q Would you agree with me that excessive ¹⁶ their Prolift mesh device? contraction or shrinkage of the tissue surrounding 17 MR. SNELL: Objection. Vague as to the mesh is a potential adverse reaction from the

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"that."

question?

MR. SNELL: Objection. Form.

A No, I would not agree with that,

Q So if that's a potential adverse

²⁴ reaction of the Prolift mesh listed in the IFU,

¹⁹ Prolift mesh?

²² Counsel.

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Q Is it vague as to that? Do you know

what I'm talking about? Do I need to restate the

A You can restate the question, Counsel.

Q Do you think that putting the warning

MR. SNELL: Objection.

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¹ in the adverse reactions section of the -- let me

- ² reask this because now I'm all befuddled here with
- ³ Burt's objections.
- 4 You think a warning in the Prolift IFU
- ⁵ that excessive contraction or shrinkage of tissue
- ⁶ surrounding the mesh is an appropriate warning to
- 7 put in the adverse reaction section of the IFU?
- 8 MR. SNELL: Objection. Misstates.
- 9 A So I think the IFU can list potential
- 10 complications of the device and of the procedure
- ¹¹ and contraction. Scarring is a known risk. It's
- 12 known to anyone doing pelvic surgery that that is
- ¹³ a known potential risk of surgery, whether the
- 14 mesh is there or not.
- Q But my question is is it an appropriate
- ¹⁶ warning to put in the IFU that excessive
- ¹⁷ contraction or shrinkage of the tissue surrounding
- 18 the mesh may occur?
- 19 A If they put --
- MR. SNELL: Objection. Go ahead.
- A If that's in the IFU warning, then
- ²² Ethicon deemed that an appropriate thing to
- 23 mention. Yes.
- Q So would that warning be an appropriate

- Page 96 MR. SNELL: Objection. Form, vague,
- overbroad.
 A They chose to list that as a potential
 - ⁴ complication. I'm not here to tell you whether
- ⁵ that's right or wrong, but I am telling you that I
- 6 don't believe that contraction of tissue is a
- ⁷ result of mesh implantation.
 - O So if I understand you correctly, you
- ⁹ believe it was inappropriate at the time of launch
- 10 but now you can't tell me if it was right or
- 11 wrong?
- MR. SNELL: Objection. Misstating his
- 13 testimony completely. Argumentative too.
- $^{14}\,$ $\,$ A $\,$ That's not what I said. I said that I
- ¹⁵ don't believe -- you asked me if I think that
- 16 should be in the IFU and my answer to you is I
- $^{\rm 17}\,$ don't know if it should be in the IFU or not but
- 18 that I don't believe it's related to the mesh.
- Q Actually, my question wasn't should it
- be in the IFU now? I asked -- well, maybe I did
- ²¹ or I didn't.
- MR. SNELL: Yes.
- Q So I'll let the record speak for
- ²⁴ themselves.

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- ¹ warning to put in the instructions for use for the
- ² Prolift device since the device was first
- ³ marketed, that Ethicon knew that was a risk?
- 4 MR. SNELL: Objection.
- 5 A So when they -- are we --
- 6 Q Let me restate the question.
- ⁷ A Restate it.
- 8 O If Ethicon knew at the time that the
- ⁹ Prolift was launched that excessive contraction or
- shrinkage of the tissue surrounding the mesh was a
- potential adverse reaction, would it have been
- ¹² appropriate to include that in the adverse
- appropriate to include that in the daye
- 13 reaction section of the IFU at launch?
- MR. SNELL: Objection.
- A No, I don't think so, because as we've
- ¹⁶ already mentioned, IFU, it does not need to be all
- ¹⁷ inclusive of every potential risk or complication
- 18 of the proposed surgery and the medical device
- being employed. And so I think Ethicon has the
- ²⁰ discretion and knowledge to know which risks are
- 21 to be listed.
- Q Is it an appropriate warning now as we
- ²³ sit here in 2018?
- A The contraction --

- My question now is do you believe,
- ² today, that it's appropriate to put a warning in
- ³ the Prolift mesh IFU that excessive contraction or

Page 97

- 4 shrinkage of the tissue surrounding the mesh is a
- ⁵ potential adverse reaction?
- 6 MR. SNELL: Objection. Asked and
- ⁷ answered, I believe.
 - A I will again state for the record that
- ⁹ I cannot tell you whether that is an appropriate
- ¹⁰ warning to have in the IFU, then or now, because I
- 11 don't believe -- it is my opinion, based on my
- 12 clinical experience, that I don't believe that's a
- 13 result of the medical device itself but, rather,
- result of the medical device fisch but, fati
- 14 surgery. So that's my statement.
- Q So if Ethicon were to list that as a
- potential adverse reaction of the medical device
- itself, you believe that would be incorrect
- 8 information?

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- MR. SNELL: Objection.
- O Is that accurate?
 - MR. SNELL: Objection. Foundation.
- ²² Improper hypothetical.
- A I would say that that is Ethicon's
- ²⁴ prerogative to list whatever potential

Page 102 Page 104 1 statement? ¹ prolapse should only be used in the context of ² research? A Well, I think that that is left ³ intentionally vague and to the discretion of the A I think that ideally it is used in ⁴ pelvic surgeon. So if you're asking me what I ⁴ research settings, but I would also take point as ⁵ consider high risk surgical patients, I can answer ⁵ an expert that not all surgeries utilizing ⁶ that question. 6 transvaginal mesh need to be part of a research Q Okay. What do you consider high risk ⁷ trial or cohort. 8 surgical patients? O So you would disagree with that A Okay. So if we're talking about statement? ¹⁰ anterior vaginal wall prolapse, cystocele, loss of A I would disagree with that statement. ¹¹ apical support, I would consider a high risk 11 Q Have you read the NIHCE, the National ¹² surgical patient, an individual who I might not 12 Institute for Health and Care Excellence ¹³ want to operate on abdominally. guidelines that were issued in December of 2017? 14 14 I take a lot of factors into A I have read them. Q And did you rely on them for issuing ¹⁵ consideration when I choose a surgical approach. ¹⁶ I have patient's age, her medical history, her your opinions in this case? 17 past surgical history. A I may have. Yes. Q Would you agree that if a procedure is 18 THE REPORTER: Patient's age what? 18 19 only used in the context of research, it's A Stage, medical history, surgical ²⁰ history, the stage and location of pelvic organ essentially experimental; right? ²¹ prolapse, whether she's had previous surgeries. 21 MR. SNELL: Objection. 22 22 And all of this plays into my ultimate decision as A No, I do not agree with that. 23 23 to whether she represents a high risk surgical Q So you don't think that if a procedure ²⁴ patient. 24 is only being used in research studies, it's Page 103 Page 105 Q So using your definition of high risk 1 experimental? ² individuals, do you believe that pelvic organ MR. SNELL: Objection. Asked and ³ prolapse vaginal mesh repair should be limited to ³ answered. A No, I don't. I don't agree with that. 4 high risk individuals? MR. SNELL: Objection to form. Q Do you agree that synthetic mesh for 6 pelvic organ prolapse should only be used in A I think it should be limited to those ⁷ complex cases with recurrent prolapse in the same ⁷ patients that you deem appropriate candidates and 8 I would need to know more specifically regarding 8 compartment? ⁹ what is considered a high risk surgical candidate. MR. SNELL: Objection. Form and 10 foundation. ¹⁰ A high risk surgical candidate is not someone I 11 ¹¹ want to operate on. A I know that statement and I don't agree 12 with that statement. Q Do you agree that current evidence on 13 the safety of transvaginal mesh repair of anterior Q So you disagree -- so you know that it ¹⁴ and posterior vaginal wall prolapse shows that 14 comes from the European Association of Urology's treatment guidelines; right? 15 there are serious but well-recognized safety 16 A I believe that's where it's coming 16 concerns? 17 17 from. I know what our European colleagues have MR. SNELL: Objection. 18 A I believe that we're all aware of said. Yes. potential risks of utilizing transvaginal mesh. 19 19 Q So you disagree with the European 20 Association of Urology in that regard? Q So you'd agree with that statement?

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24

²² answered.

A Yes.

²⁴ repair of anterior or posterior vaginal wall

A There are risks of traditional surgical

Q You would agree that transvaginal mesh

21

23

²² repairs as well.

MR. SNELL: Objection. Asked and

Q Would you agree that the currently

Page 106 Page 108 ¹ available literature does not support the routine 1 accurate? ² use of transvaginal mesh for prolapse repair? MR. SNELL: Misstates, foundation. Go MR. SNELL: Object. ³ ahead. A Are you telling me that the chief Q Let me actually ask a different ⁵ question. Would you agree with me that currently ⁵ medical officer stated that Prolift should never 6 available literature does not support the routine 6 have been sold? ⁷ use of transvaginal mesh for prolapse repair but Q I'm telling you that the chief medical 8 that that does not apply to the use of 8 officer agreed that when you take into account the ⁹ transabdominal mesh used during a minimally most serious complications that Ethicon knows have happened with the Prolift, when you look back, a ¹⁰ invasive or open sacrocolpopexy? 11 MR. SNELL: Objection. Form and reasonable argument can be made that as a result of those very serious complications, the risks ¹² foundation. 13 A So you need to -- please just state outweighed the benefit and it shouldn't have been 14 sold? that question again. 15 O Well, let me back up. Have you read 15 MR. SNELL: Objection. Foundation. 16 the Canadian Urological Association's treatment 16 Misstates the evidence. Asked and answered as guidelines for pelvic organ prolapse repair issued well. He's already told you his view on that. ¹⁸ in 2017? A Yeah. My view on that is that my 19 A '17. Yes, I did read that. clinical experience and my review of the 20 literature support the use of Prolift. Q Are you aware that that guidance states Q And you've never seen the testimony of 21 that the currently available literature does not 22 the chief medical officer of Ethicon and Johnson & ²² support routine use of transvaginal mesh for ²³ prolapse repair. This recommendation does not Johnson, Jim Hart? ²⁴ apply to the use of transabdominal mesh used A No, I have not. Page 107 Page 109 ¹ during a minimally invasive or open Q And that's not something that you ² considered in reaching your opinions in this case? sacrocolpopexy? 3 A I'm familiar with that statement. A No. I considered my opinions based on 4 review of the literature specifically with 4 Q Do you disagree with that statement? 5 MR. SNELL: Object. ⁵ attention to Level 1 and Level 2, not to expert 6 testimony and less quality evidence. So I did 6 A I disagree with that statement. Yes. 7 ⁷ focus my expert report on review of the Q Do you agree that a reasonable argument 8 can be made that as a result of very serious 8 literature, Level 1, Level 2 evidence and complications that can occur from the Prolift, the statements and email communication from industry. 10 risks outweigh the benefit and there's -- well, 10 Q So you don't think that the testimony 11 strike that. 11 of Ethicon's chief medical officer can offer any Would you agree with me that when you relevant opinion regarding the safety and efficacy 13 take into account the most serious complications of the Prolift device? 14 Ethicon knows have happened to women with the A I can't comment on that because I ¹⁵ prolapse, when you look back, a reasonable didn't read his statement. ¹⁶ argument can be made that as a result of those 16 Q Is that something that you would have liked to have reviewed prior to issuing your very serious complications, the risks outweigh the ¹⁸ benefit and it shouldn't have been sold? opinions in this case? 19 19 MR. SNELL: Objection. A I'm not sure it would have had any 20 A No, I don't agree with that statement, bearing on my opinion, on my report. ²¹ Counsel. 21 Q But would you have liked to have seen 22 it? 22 Q So if the chief medical officer of

23

24 answered.

23 Ethicon and Johnson & Johnson agreed with that

statement, you would disagree with them; is that

MR. SNELL: Objection. Asked and

Page 134

A Okay. So we're talking about erosion. ² There's lots of things that lead to erosion,

³ Counsel, and contraction and scarring is due, in

⁴ my opinion, to surgery.

11

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You don't have contraction and scarring ⁶ if you don't use a scalpel. If you use a scalpel, you're going to have some contraction and 8 scarring. Tissue never regains its initial strength. And I don't believe that contraction and scarring is a result of the mesh.

Q Never? It's never? So you believe 12 that it's never a result of the mesh?

MR. SNELL: Objection. Asked and answered about seven times. He's already testified to that numerous times. Counsel.

16 A Again, I don't believe it's related to 17 the mesh. That is my statement, my testimony.

18 Q So then you believe that a mesh which ¹⁹ causes excessive shrinkage and contraction can't be a defect in the device because it doesn't occur; right?

22 MR. FAES: Object.

23 A Right. I don't think -- again,

²⁴ answering that question again, I do not believe

Page 136

¹ pelvic pain in patients presenting to our clinic

² at Hopkins with pelvic organ prolapse, we see that

³ there's a very high incidence of those conditions

4 at baseline. And so I do not believe that mesh

⁵ implantation, whether it's Prolift or Elevate,

⁶ contributes necessarily to dyspareunia.

Q So let me see if I can answer it, ask

it as a yes-or-no question, because I'm running

out of time. I'll try to keep it very simple.

Doctor, do you believe that pain can potentially result from a Prolift mesh?

12 MR. SNELL: Objection. Asked and answered.

14 A I believe that pain, just like erosion, can be multifactorial and that there can be -- by that, I mean there can be many things that lead to pain and painful intercourse, dyspareunia that are not necessarily related to the use of transvaginal 19 mesh.

20 Q That's not what I'm asking. I'm asking the question very specific and I'm using your language from your report.

23 Do you believe -- and I'm asking you a 24 yes-or-no question. Do you believe, yes or no,

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¹ that excessive contraction and shrinking, whatever

² you just said, if you want to restate it. But I

³ think I've tried to make my point. I do not

4 believe that histological changes are a result of

⁵ a defect in the mesh.

Q On page 12 of your report, you state ⁷ that "Assuming that pain or dyspareunia are due to 8 the Prolift or the Gynemesh PS is speculative and non-evidence based."

10 Do you see that, page 12, last sentence 11 of the continuing paragraph.

12 MR. SNELL: Okay. Sorry.

13 Q Do you see that, Doctor?

A Yes, I do. 14

Q So is it your opinion that pain and 16 dyspareunia can never be due to the Prolift or

Gynemesh PS?

18 A My opinion is that there are many 19 causes for pain and dyspareunia and sexual ²⁰ dysfunction, and that if we look at studies that 21 look at those complaints in the general population ²² presented to either primary care physician offices 23 or presenting in our study, that we looked at

²⁴ evidence at the prevalence of dyspareunia and

1 that pain can be due to a Prolift mesh? I'm not

Page 137

² asking about multifactorial or anything else. I'm

asking if pain can be due to a Prolift mesh?

MR. SNELL: Objection. Asked and answered.

A So my statement here is that it's

speculative and nonevidence-based. And so as far

as you can say a yes-or-no answer to that, I don't

think you can. I think that you need to take

cases on a case-by-case basis and understand that

11 there are lots of things that can contribute to

pelvic pain and dyspareunia and that we can't just

13 say oh, well, you had a mesh placed and,

14 therefore, your pain is related to the mesh.

Q So I just want this to be clear.

16 You're stating that you can't answer yes or no to

the question of whether or not pain can be due to

18 Prolift?

19 MR. SNELL: Objection. Form.

Misstates.

21 A Right. I can't answer that

²² definitively. No.

23 Q Would you agree with me that you can't 24 state yes or no that dyspareunia can be due to

Page 140 Page 138 ¹ Prolift? A Well, I have been an associate 2 A For the same reasons I've just ² residency director at Johns Hopkins, as my CV ³ enumerated, I can't say that dyspareunia would be 3 attests to. I've taught residents for all of my ⁴ directly related to Prolift. 4 career post-residency myself. I've been involved ⁵ with fellowship training. And so I am very aware Q Doctor, on page 3 of your report, you 6 discuss the erosion rates for the TVT and TVT-O 6 of what they require by the RFC, Residency Review product. ⁷ Committee, in terms of what their fund of 8 8 knowledge needs to be, what their surgical A Yes. Q Would you agree with me that there's experience needs to be at the time of graduation 10 nowhere in your report where you discuss what the from residency. 11 overall rates of mesh exposure are for the Prolift 11 Q And did you apply that as a standard or Gynemesh PS product? 12 for your IFU opinions? 13 A That could be. 13 A Yes, I did. 14 MR. FAES: How are we doing on time? 14 Q Have you talked Prolift to any 15 THE REPORTER: You are right at the 15 surgeons? ¹⁶ end. 16 A Yes, I have. 17 17 MR. FAES: I'll reserve my one minute Q Can you tell us the types of surgeons? for what I'm sure will be Burt Snell's 18 A I've taught Prolift surgeries to hour-and-half direct. And can we take a quick 19 residents more than I can count, fellows of which I've had over 20 in my career, many of which you 20 break? 21 MR. SNELL: If you want to. know. I've taught Prolift to some generalists in 22 (Break taken, 4:16 - 4:21 p.m.) 22 the community here as well as to other EXAMINATION BY MR. SNELL: 23 ²³ urogynecologists. 24 Q All right. Burt Snell, attorney for Q Did you utilize that as a standard and Page 139 Page 141 basis for your IFU opinions with regard to the ¹ Ethicon and Johnson & Johnson. ² adequacy of the Prolift IFU? Dr. Ellerkmann, I just have some ³ followup questions on some of the topics that MR. FAES: Objection. 4 you've been discussing with Plaintiff's counsel A Yes, I did. 5 today, the first of which -- well, I'll come back Q Are you familiar with the board 6 to that. certification process -- strike that. 7 Are you familiar with the knowledge Let's kind of start in the beginning 8 with some of the topics. You recall being asked base tested and evaluated with the OB-GYN board about your opinions as to the adequacy of the certification process? MR. FAES: Objection. 10 Prolift IFU? 10 11 11 A Yes. A Yes, I am. Q And I believe you testified to Q Same question with regard to female 13 Plaintiff's counsel you believe that it was public medicine and that subspecialty board. Are 14 adequate? you familiar with the knowledge base, the expected 15 A Yes. knowledge base of surgeons sitting for that board? 16 Q Do you have expertise as to the 16 MR. FAES: Objection. 17 expected knowledge of the pelvic surgeon who might 17 A Yes, I am. 18 perform the Prolift? 18 Q For those board certifications, is 19 A Yes, I do, because I am one. there an expected required knowledge with regard 20 Q Do you have expertise and knowledge to complications that can come from pelvic organ 21 with regard to the expected knowledge of pelvic prolapse surgery? 22 surgeons coming out of residency? 22 MR. FAES: Objection. 23 A Yes, I do. 23 A Yes, there are. 24 Q How is that? 24 Q With and without mesh?

Case 2:12-md-02327 Document 7023-3 Filed 10/25/18 Page 15 of 17 PageID #: 184122 Mark Ellerkmann, M.D. Page 150 Page 152 ¹ or presented at. One, let's take number 4, Pelvic 1 treating pelvic organ prolapse? ² Organ Prolapse and Biomaterial Augmentation. A Yes, it would have. Q Would that presentation have included A Correct. 4 your analysis and knowledge as to the design and Q Is that a course? 5 ⁵ the utility, if any, of such a device? A Where was that? 6 Q Sure. Number 4, Pelvic Organ Prolapse MR. FAES: Objection. and Biomaterial Augmentation. A Yes. 8 My question to you -- are you there? Q You told Plaintiff's counsel you also A Oh, yes. Yes, I remember that very have experience analyzing the design of devices in cadaver labs? ¹⁰ well. I went and spoke to the European 11 Association of Gynaecologists. That was in Bern, 11 A Yes. 12 Switzerland, and we spoke. That was at that time Q Number 25, for example, lists a cadaver 13 with Cook and we were speaking primarily about 13 lab you did on Prolift and other devices. Do you see that? ¹⁴ Surgisis. That was a xenograft that Cook was 14 15 ¹⁵ developing for pelvic floor reconstruction. A I do. It was here in Baltimore. 16 16 Q In 2000, were you analyzing Q Did you do other cadaver labs on biomaterials and specifically how they performed Ethicon devices where you analyzed the design of in the pelvic organ prolapse application? the device and the safety in places other than MR. FAES: Objection. Baltimore? 20 20 A Yes, I was. In fact, Counsel, as a MR. FAES: Objection. 21 fellow, I was very involved in developing and 21 A Yes, I did. 22 ²² working with my co-fellows and subsequently as a Q You were asked about the materials list ²³ junior attending. We did several pilot studies 23 that my firm put together and I believe you ²⁴ looking at some of the earliest biological grafts, 24 testified you did not read the two company witness Page 151 Page 153 ¹ xenografts, including Tutoplast and Surgisis, and ¹ depositions that we put on that. Is that correct ² or wrong? ² seeing whether there were improved outcomes in ³ anatomical repair and subjective outcomes with A That's correct. 4 their use for transvaginal augmentation. Q Okay. Did you review, though, the Q Another one, if you just go to number company documents that we sent to you? 6 22, Biomaterials in Gynecologic Surgery: A Review MR. FAES: Objection. ⁷ of the Literature and Current Applications. You A I reviewed as much as I could, yes, of 8 were the invited speaker at the American those documents. ⁹ Urogynecology Association Annual Scientific Q Had you been reviewing company 10 Meeting in 2005. Do you see that reference in documents and materials pertinent to the Prolift 11 number 22? actually even before becoming an expert in this 12 A Yes, I do. 12 litigation? 13 Q And in connection with that, would you 13 MR. FAES: Objection. 14 have analyzed biomaterials? A I reviewed documents in the past from

- 15 A Yes.
- 16 Q Would you have presented to pelvic
- surgeons on biomaterials and their use in these
- 18 applications?
- A I did. That was a presentation. 19
- 20 Q Would that presentation have included
- 21 the pelvic organ prolapse application?
- A Absolutely. Yes. 22
- 23 Q Would that presentation have included
- 24 the use of a macroporous polypropylene mesh for

- Ethicon as a preceptor and at our summit meetings.
- Yes. 16

21

24

- 17 Q And did you bring today response to
- plaintiff's deposition notice that was marked as
- 19 Exhibit No. 1 the materials that you've considered
- ²⁰ and relied upon?
 - A I did. Yes.
- 22 Q Can you describe that for the court
- ²³ reporter, please, what you brought.
 - A So I have brought copies, both hard

Page 154

- ¹ copy and a flash drive containing all the
- ² literature that I had been able to review in
- ³ preparation for my expert report and for this
- ⁴ deposition.

8

- Q Does that also include company
- ⁶ documents such as the IFU and professional
- educations lines?
 - A Yes, it does.
- Q Does that include documents from
- ¹⁰ Ethicon pertaining to the design of the Prolift?
- 11 A Yes, it does.
- 12 Q You were asked about if you did an
- ¹³ analysis. Did you do an analysis of the medical
- 14 literature with regard to Prolift to formulate
- your opinions?
- 16 A Yes, I did.
- 17 Q Can you tell us in general how you went
- about doing that analysis?
- 19 A So that analysis has been ongoing since
- ²⁰ I was introduced to transvaginal repairs. And so
- ²¹ in addition to the literature reviewed for today's
- ²² deposition and for the report, the foundation for
- 23 my opinion and expert report is based on my
- ²⁴ experience, my clinical experience, my
 - Page 155
- 1 communications with other colleagues, and my
- ² review of the literature over the years as well as
- 3 specific review of the literature for preparations
- 4 for the report.
- Q And there's been questions about
- ⁶ Gynemesh PS and Prolift. Does Prolift use
- 7 Gynemesh PS?
- A Yes. 8
- Q Do you view outcomes and studies on
- 10 those two devices as being relevant and similar?
 - A I do. Yes.
- Q Is that the way you considered those
- 13 devices back when you were using and teaching them
- 14 before becoming an expert?
- A Correct. So we know that Gynemesh PS 15
- 16 is the same mesh that's used in Prolift. The
- ¹⁷ difference is in the design, in the cut of the
- 18 mesh.

11

- 19 Q And would Gynemesh PS and your personal
- 20 use of it, did you need to cut that mesh and trim
- 21 it before using it as well?
- 22 A I have on occasion, yes. It came in
- 23 sheets, so we cut it all the time when we used it
- ²⁴ for abdominal sacrocolpopexy.

- Page 156 Q You were asked about whether you
 - 2 separated Prolift studies into different buckets
 - or categories. Do you recall in general those
 - 4 types of questions?
 - A I do.
 - Q Did you review the overall data an
 - Prolift to evaluate and help form your opinions?
 - 8 MR. FAES: Objection.
 - A Yes, I did.
 - 10 Q Even as you sit here, do you recall any
 - 11 specific studies that actually stated that Prolift
 - 12 was defective?

13

14

- MR. FAES: Objection.
- A I didn't see any study that
- specifically stated that Prolift was defective.
 - Q In formulating your opinions that
- Prolift was not defective, have you described your
- methodology earlier?
 - MR. FAES: Objection.
 - A I believe I did describe my
- methodology.
- Q You were asked about pathology. Have
- ²³ you seen any medical literature that concerns
- ²⁴ pathology of explanted mesh?

Page 157

- A Yes, I have seen literature that looks
- at histology of explanted mesh.
- Q Is that something you would have seen
- 4 not just in connection with your role here, but is
- ⁵ that something that will be part of your regular
- reading of the literature?
- MR. FAES: Objection.
 - A Absolutely. I mean, as I noted to
- Counsel earlier, even years ago with my fellow,
- ¹⁰ we've looked personally at explanted mesh
- 11 microscopically in trying to obtain a better idea
- of what was going on histologically with that
- material.
- 14 Q And when you were doing these
- presentations to other pelvic surgeons, whether at
- 16 the annual AUGS scientific meetings or otherwise,
- as part of that and devising your opinions at that
- time with regard to the biocompatibility of mesh
- for the prolapse application, did you consider
- clinical studies published on the mesh?
- 21 MR. FAES: Objection.
- 22 A We considered -- I considered clinical
- studies and I also looked at the review of the
 - biological grafts as well as synthetic grafts that

2 experience that you rely upon for your opinions? 3 A It is. I personally view every 4 pathology report on my patient. 5 MR, FAES: We're going to have to take 6 another break if you keep going much longer. 7 Q I'm just checking. 8 And in your expert report, did you 9 discuss your opinions on the design of the Prolift 10 device? 11 A Yes, I did. 12 Q Did you discuss the potential benefits 13 - strike that. 14 Did you discuss the benefits as you saw 15 them with regard to the components and parts to the the Prolift device including Gymemsh PS? 15 A Yes, I did, previously elaborated on 16 that briefly here today. 16 MR, FAES: Thank you, Doctor. 17 (Deposition concluded at 5:28 p.m.) 18 STATE OF MARYLAND) 19 COUNTY OF HARFORD) 19 GOUNTY OF HARFORD) 10 COUNTY OF HARFORD) 10 Counset to any of the parties, nor in 16 may may interested in the outcome of this action. 16 may be used in court. 17 (The foregoing certification of this 17 may may interested in the outcome of this action. 18 transcript is a true record of the proceedings and 17 may may interested in the outcome of this action. 19 My commission expires 8/27/2019 20 (The foregoing certification of this 17 may may may may may may may an unless under the direct 20 control of the certifying 4 c		Page 186		Page 188
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